Advising the Congress on Medicare issues

Medicare payment systems and follow-on biologics

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MEDPAC

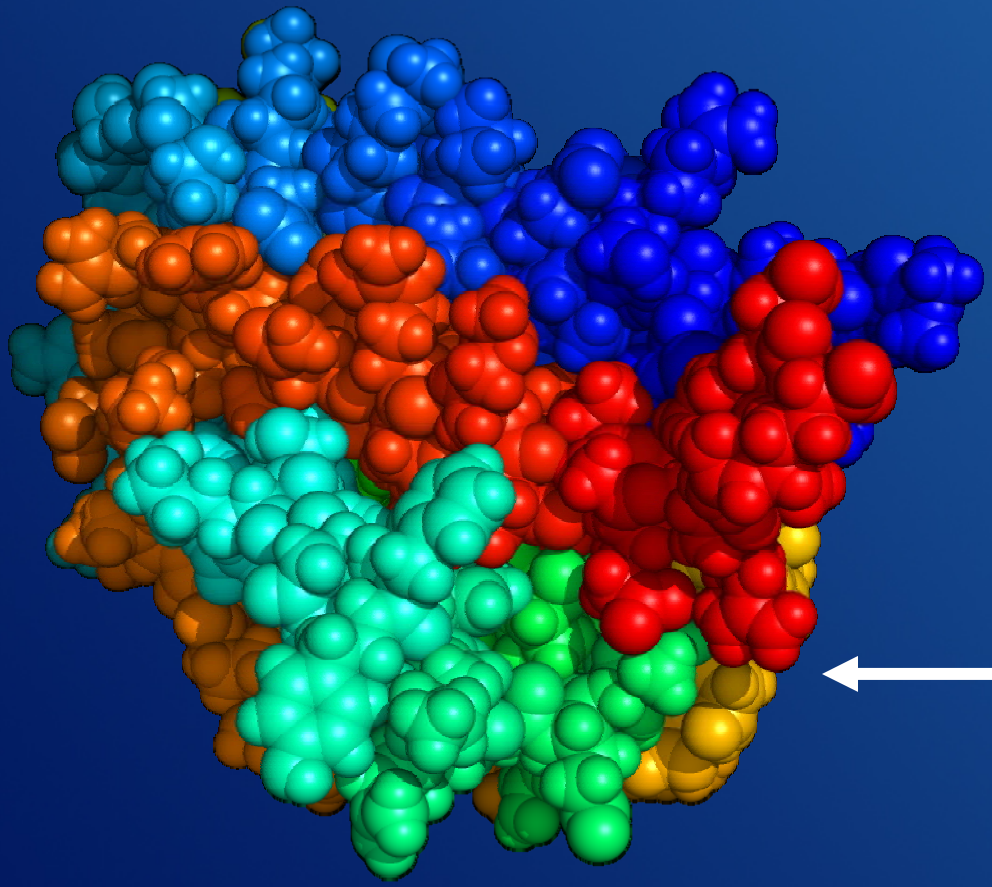
Key findings

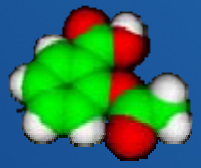
- Use of biologics in Part D is limited but increasing
- Plan risk for biologics is limited
- Plans have been unable to negotiate lower prices for high-cost biologics
- LIS recipients are more likely than other beneficiaries to use new biologics
- The Medicare payment system may need modification to produce savings for biologics
- Increased post-marketing surveillance for drugs may be warranted

Questions from March meeting

- International pricing comparisons
- VA pricing

What is a biologic?





Small molecule drug: a drug synthesized via a chemical process (pictured: aspirin)

Biologic: medicinal product that is synthesized from a living organism or its products (pictured: EPO)

There are key differences between biologics and small molecule drugs

- A follow-on biologic cannot be exactly identical to its reference product because of the large size and complexity of the molecules.
- Biologics tend to be more expensive to produce than small molecule drugs.
- Biologics have specific safety risks involving immunogenicity

New post-marketing surveillance will utilize Medicare claims data

- Existing post-marketing surveillance programs are unsystematic and rely on doctors, patients, and manufacturers to report adverse events.
- In 2007, the Congress required FDA to establish a “post-market risk identification and analysis system” to link and analyze safety data from multiple sources.
- Sentinel Initiative – a strategy for monitoring medical product safety using Medicare claims data

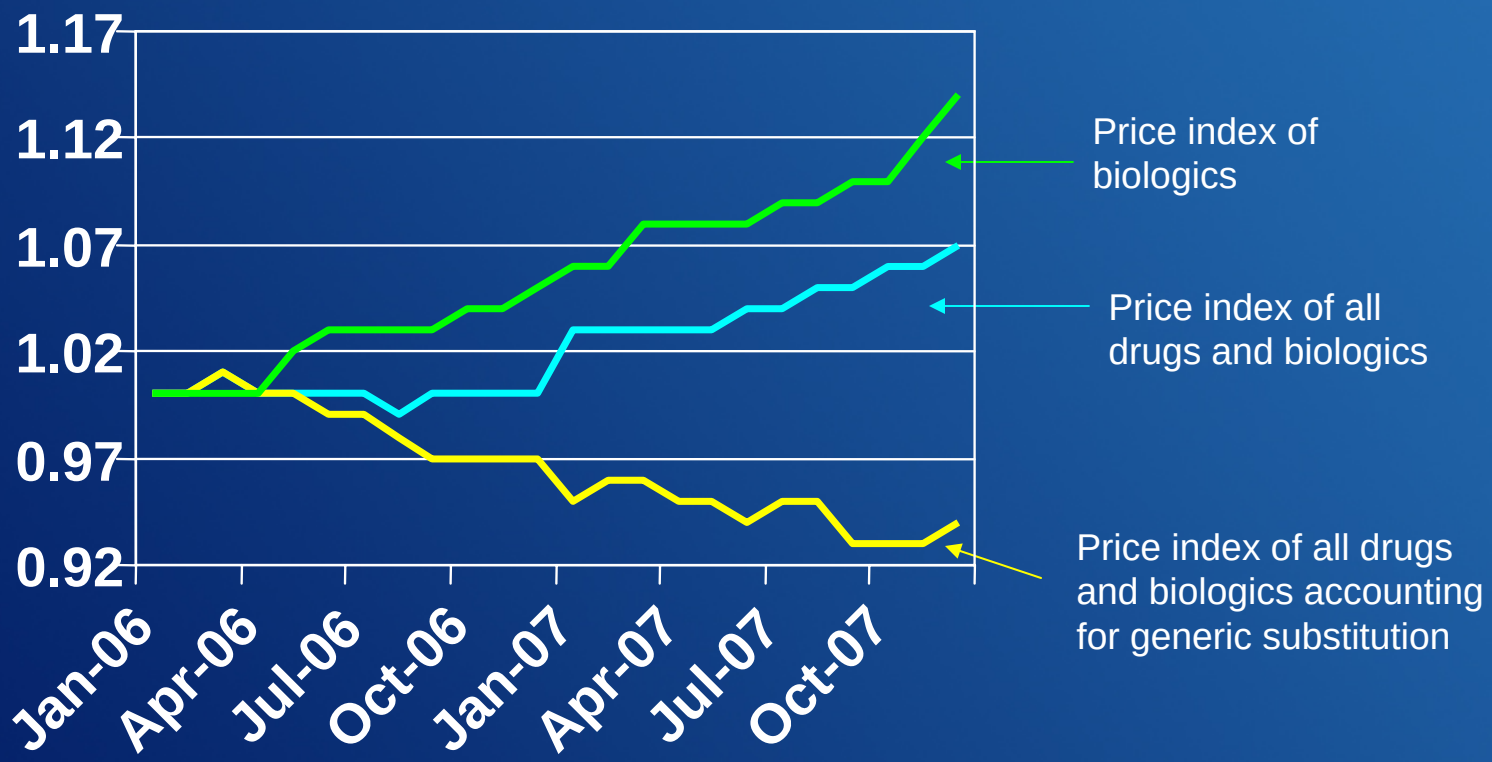
Which biologics are covered under Part D?

- Older, simpler molecules (e.g., insulin)
  - Well understood
  - Multiple branded products → lower prices
- Newer, more complex molecules (e.g., epoetin)
  - High launch prices
  - High cost-sharing
  - Likely to be listed on specialty tiers
  - Many in development

Biologics account for a small but growing share of total Part D spending

- In 2007, spending on biologics totaled approximately $3.9 billion, or about 6% of Part D spending.
- Between 2006 and 2007, spending grew by about 36 percent, compared to total Part D spending which grew by 22 percent.
- Prices for biologics have increased more rapidly than prices for small molecule drugs

Prices for biologics have increased faster than those for other drugs



Source: Acumen LLC analysis for MedPAC

Lack of competition among Part D biologics

- Many new biologics are in protected classes
- Plan risk for high cost biologics is limited
  - No plan liability for spending in coverage gap
  - 15% plan liability for spending over catastrophic threshold
- Plans may experience selection bias if they provide more generous coverage of new biologics

LIS recipients are most likely to use new biologics

- LIS recipients use more drugs including biologics than other beneficiaries
- They are more likely to have spending that reaches the coverage gap (44% compared to 24% for non-LIS beneficiaries)
- They are more likely to exceed the catastrophic threshold (18% vs. 2.7%)
- They have nominal cost-sharing so cost-sharing differences may not affect their choice of drugs

Future work

- Strategies to increase incentives to use FOBs in Part D
  - Modify risk adjusters
  - Modify Medicare payment policy for spending over the catastrophic limit
- Strategies to increase use of FOBs in Part B
- Broader strategies to improve value of drugs such as reference pricing and bundling
- Strategies to monitor drug safety